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09/681,879	06/20/2001	James Claude Carnahan	RD-28397	1539

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EXAMINER	
SODERQUIST, ARLEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/681,879	CARNAHAN ET AL.
	Examiner	**Art Unit**
	Arlen Soderquist	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .

4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: .

1. Applicant is advised that should claims 13 or 32 be found allowable, claims 14 or 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 7, 12-14, 17-18, 24-29, 31, 35 and 43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hol. In the paper Hol teaches a simple device for routine measurements of the oxidation-stability of polymers by oxyluminescence. The oxyluminescence generated upon oxidation of many polymer types can be measured in a simple way by means of a device examining several samples at once. The oxylumeter gives a rapid determination of the induction periods of the polymers, so that routine examination of the oxidation stability is made easy. Figure 1 shows the apparatus for measuring 12 samples at temperatures from 20-200 °C with a photomultiplier. Figure 2 shows the spectra for 12 polyethylene samples stabilized in different ways at 150 °C. The first paragraph of the right column of page 813 teaches that this device has produced very satisfactory results on polyethylene, polypropylene, ethylene-propylene copolymers, nylon and other polymers. The principle aim of the investigation was the evaluation of anti-oxidants and the device permits the determination of the influence of temperature on the induction time by Arrhenius plot.

4. Claims 1-2, 7, 12-14, 17-19, 24-29, 31, 35 and 43-44 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Broutman (US 4,350,495). In the patent Broutman teaches a chemiluminescence apparatus and method for determining polymer stability by measuring the intensity of the light emitted during thermal oxidation. The apparatus described in the invention measures the light intensity vs. time from polymers in an oxidative atmosphere. On the basis of this information, important parameters such as induction time and oxidation rate can be obtained. The apparatus has the advantage of simultaneous multi-sample analysis and the mathematical

approach enables data computerization. The apparatus has a dark chamber (1) with a sliding stage (2) which holds numerous individual test cells (3). The test cells are maintained on a metal support plate (4) which provides even temperature distribution to the cells. A heater (5), such as an electrical resistance heater, is placed under the metal plate and thermocouples (6) and a temperature controller (7) are used in the conventional manner to maintain the desired temperature. The test cell construction provides the opportunity to carry out the experiments not only under gas flow but also under gas pressure. The test cells are constructed in a manner that they can be pressurized up to several atmospheres. The lower part (19) of the dark chamber is separated from its upper part (20) by a metal plate (21) with a number of holes (22) equal to the number of test cells. Each hole in the separating plate is covered by a glass window (23). When the sliding stage is in "in" position, each of the holes in the separating plate is strictly above one of the test cells. The light emitted by the samples placed in the test cells is sequentially measured by a rotating photomultiplier (24) placed in the upper part of the dark chamber. The light output is synchronously recorded with the sample position. This assures sequential sampling of light intensity from the multi-sample apparatus. In order to avoid the photomultiplier overheating during the experiments a fan (29) is placed in the upper part of the dark chamber and provides constant outside air circulation through the upper part of the dark chamber. Electronic part of the apparatus consists of a power supply (30), the photomultiplier current amplifier (31), a signal conditioning circuit (32), a sequential circuit (33), a temperature controller with a digital display (34), a computer (35) with a printer (36), and a display (37), control knobs (38) and pilot lights (39). A typical light intensity vs. time curve for the chemiluminescence produced by auto-oxidation of a polymer (normally made at constant sample temperature) is presented in figure 8. There is an induction period during which the light intensity is low and constant, oxidation is slight and build-up of peroxides or hydro-peroxides is slow. This induction period will vary in length depending on the chemical structure of the polymer, the presence of impurities and the temperature of oxidation. Following the induction period there is an autocatalytic stage in which the peroxides catalyze further oxidation. The rate of this first order chemical reaction at any given temperature is influenced by impurities arising from different methods of polymer manufacture. The induction and acceleration periods are not separate phenomenon, but parts of a typical autocatalytic reaction. The light intensity next

reaches the highest level (peak peroxide concentration). Finally, there is a period of light decay (a deceleration of the rate of oxidation). The shape of the chemiluminescence curve provides data from which significant information can be derived. This information can be determined by the computer.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hol or Broutman as applied to claim 2 above, and further in view of Jipa. Hol and Broutman do not teach measuring all of the claimed characteristics.

In the abstract Jipa discusses evaluation of thermal stability of isotactic polypropylene containing triazinic additives by using a chemiluminescence technique. Thermal stabilization of i-PP due to a series of mercaptotriazines was studied by chemiluminescence at 180 C. Four concentrations (0.15; 0.25; 0.50 and 0.75% wt./wt.) were prepared. The most relevant kinetic parameters of oxidation (induction time, degradation rate, maximum chemiluminescence intensity, time for attaining maximum chemiluminescence intensity) were calculated. Their activities and stabilities were evaluated relative to unprotected i-PP and i-PP stabilized with a standard antioxidant (Irganox 565) at the some concentrations. A certain order in the stabilization efficiency was stated and some of the studied mercaptotriazines had higher capability to prevent oxidation than commercial compounds.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure or calculate the relevant kinetic parameters as taught by Jipa in the Hol or Broutman methods because of the information which they provide in comparing potential stabilizers as taught by Jipa.

7. Claims 3-6, 8-11, 15-16,19-23, 30, 32-34, 36-42 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hol or Broutman as applied to claims 1-2, 7, 12-14, 17-19, 24-29, 31, 35 and 43-44 above, and further in view of Cavicchi, and George, Brauman, Thorpe, Jorgenson or Reid. Hol and Broutman do not teach simultaneous analysis of the plurality of samples, methods of preparing stabilized polymers or other types of detectors.

In the patent Cavicchi teaches the use of microsubstrates for materials processing. The figures show micro-hotplates that may have a film of material deposited thereon. Column 10, lines 41-46 teach that after deposition of the components the resulting samples can be subjected to a variety of post processing treatments including annealing or treatment in a variety of atmospheres addition of subsequent materials and thermal cycling. Column 11, lines 46-63 teach multiple samples fabricated under different conditions that may be examined using a variety of microcharacterization methods including electron microscopy, x-ray methods and optical microscopy. Also taught is that the arrays are tremendously more efficient and economical than separate sample analysis. Column 12, lines 22-32 discuss the repeatability of the processing steps and the advantage offered by the Cavicchi system. Column 12 lines 46-55 teach several advantages of the size and configuration of the device. These include rapid temperature changes lower power consumption and lower power radiation. Additionally it is taught that the temperature can also be programmed to vary slowly during a given process. Column 13, lines 1-4 teach that the invention is not limited to materials processing only. Other areas of application include materials science solid state physics (column 14, lines 26-33, melting) and chemistry (column 14, lines 47-54 and column 15, lines 1-9). Column 14, lines 9-25 discuss the ability to simultaneously process the samples allows an enhanced optimization of the samples. Column 15, lines 1-9 discuss the contacting of materials with gases and investigating the nature of the chemical interactions occurring. The paragraph bridging columns 7-8 teaches a size for the micro-hotplates of between 50 and 800 μm. Column 1, lines 65-68 teach that one object of the

device is to prepare a plurality of micro-samples on a single substrate having different characteristics.

In the paper George discusses the effect of stabilizers on integrated chemiluminescence in the early stages of polypropylene photo-oxidation. The integrated chemiluminescence obtained by heating photooxidized polypropylene films in an inert atmosphere is affected by a number of common stabilizers, particularly free-radical scavengers, such as hindered phenols, and OOH decomposers, such as thiodipropionate esters. These stabilizers must be removed prior to chemiluminescence analysis of the OOH content in the early stages of photooxidation. From an analysis of the effect of stabilizers on the peak in OOH concentration observed after short times of UV irradiation with wavelengths >300 nm, only the thiodipropionate ester and a 2-hydroxybenzophenone UV absorber affected the kinetics of OOH formation and decomposition and increased the induction period as measured by carbonyl index. A hindered (PhO)3P produced an immediate increase in integrated chemiluminescence and was a pro-degradant unless a hindered phenol was incorporated to inhibit peroxy radical attack on the stabilizer. A commercial hindered piperidine caused a lowering of the chemiluminescence when the sample was heated for analysis, consistent with a weak radical scavenging and OOH-decomposing activity of the amine, but did not affect the kinetics of formation and decomposition of OOH on UV irradiation. On page 40 the process for mixing the polypropylene with the stabilizers is taught and includes dissolving the stabilizer in a solvent and mixing it with the polypropylene powder.

In the paper Brauman discusses chemiluminescence studies of the thermooxidation of PEEK. A highly sensitive microcomputer-controlled chemiluminescence apparatus capable of spectral resolution of emitted light was used to study the oxidation of thermoplastic matrix material PEEK at 110° in oxygen. Even after prolonged exposure and extensive decay in the chemiluminescence signal, the samples showed no change in properties or accumulation of oxidation products. Evidence suggested that after O-assisted initiation, reaction proceeded by radical transfer primarily of polymer phenoxy radicals in a type of radical aromatic substitution reaction on PEEK. Similar substitution-type biomolecular termination of polymer phenoxy radicals can lead to excited polymer and benzoquinone, emitters that account for much of the oxyluminescence spectrum of PEEK. Under the experimental conditions, the benzoquinone was

volatile and the product polymer should be indistinguishable from starting polymer. On pages 1206-1207 is taught a gas switching experiment in which the samples were heated in an inert gas, nitrogen, until a certain temperature followed by switching to oxygen and monitoring the chemiluminesence during and after the switch. This was done to destroy any spurious luminescense.

In the paper Thorpe presents enhanced luminescence determination of horseradish peroxidase conjugates using benzothiazole deriatives in microtiter plates. The benzothiazole derivatives, 2-cyano-6-hydroxybenzothiazole, 6-hydroxybenzothiazole and dehydroluciferin, enhance light emission from the horseradish peroxidase-catalyzed oxidation of cyclic diacylhydrazides such as luminol. The relatively intense and prolonged light emission from reactions enhanced by benzothiazole derivatives is easily detected and is utilized in a rapid assay for specific antibody against cytomegalovirus done on black polystyrene microtiter plates. Rapid measurements are possible when a prototype manually-operated microtiter plate reader is used. Light emission from individual wells was quantified by an end-window photomultiplier tube positioned either just above the microtiter plate surface, or some distance away, the light being collected through a fiber optic light guide. The assay was also done on transparent poly(vinyl chloride) microtiter plates with simultaneous measurement of light emission from several wells; this was achieved with simple instrumentation and a 20,000-ASA Polaroid instant photography film.

In the paper Jorgenson teaches a 96-Channel microplate surface plasmon resonance fiber optic sensor system. The system is for simultaneous analysis of ninety-six micro-well plates and enables high throughput biochemical screening analysis. The sensing element is composed of ninety-six discrete fiber optic sensors housed in a containment plate. A white light source is used to introduce light to the sensor via a multiplexed fiber optic bundle. The transmitted spectral intensity distribution of each sensor is detected via a multiplexed fiber optic bundle. The transmitted spectral intensity distribution of each sensor is detected simultaneously using a lens-based holographic imaging spectrograph and a 2D CCD detector. Experimental results confirm the feasibility of the application of this label free and real-time transduction mechanism of surface plasmon resonance towards high throughput biochemical analysis. See figures 2-4 and their associated discussion for a description of the system.

In the paper Reid teaches a sensitive fiber optics-based system for real-time detection of PCR-amplified DNA using molecular beacons. Molecular beacon hairpin shaped fluorescent oligonucleotide probes are powerful tools for quantifying specific nucleic acid sequences. Stratagene is developing a sensitive system, using these probes, for detecting and quantifying initial template copy number of nucleic acid sequences in real time during PCR amplification. The system allows parallel multiple fluorophore detection for many applications including allele discrimination and quantitative gene expression analysis. The instrument, combined with the kits, provides an effective system for molecular biological research. The discuss the design and utility of an instrument that combines the capabilities of a microplate fluorescence reader with a PCR thermocycler into a low cost real time detection system. The instrument integrates a multiple fluorophore parallel fiber optic excitation and emission detection system, a precision X-Y translation stage, and a high performance thermoelectric temperature cycler with a computer controlled data collection and analysis system. The system uses standard PCR tubes, tube strips, and 96 well plates as the sample format. The result is a low cost, reliable, and easy to use system with premium performance for nucleic acid quantification in real time. See figure 2 and the associated discussion for a description of the system regarding its structure and advantages.
It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the simultaneous optical detection methods and systems of Cavicchi, Jorgenson, Thorpe or Reid into the device and method of Hol or Broutman because of the reduction of time and cost for the analysis when detecting multiple samples simultaneously as taught by Cavicchi, Jorgenson, Thorpe or Reid. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the sample preparation methods of George or the gas switching method of Brauman into the Hol or Broutman methods because of the ability to add stabilizers to the polymer that are tested and remove effects of spurious or interfering luminescence as respectively taught by George and Brauman.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional art relates to methods and apparatus for testing polymers using chemiluminescence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989.

The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Arlen Soderquist
September 24, 2003

ARLEN SODERQUIST
PRIMARY EXAMINER